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Project Officer Name Melissa Revely-Wilson				Bran	ch/Mail Code:		
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# PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-31

**TITLE**: Epidemiologic Support for IRIS

Principal Section & Paragraph of SOW: A.1,2; B.1,2,3,4,5; C.1; D; and G.1,2

PERIOD OF PERFORMANCE: CO Approval – November 1, 2014

#### I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter, EPA) National Center for Environmental Assessment (NCEA), within the Office of Research and Development (ORD). The specific purpose is to provide expert epidemiologic support for the development of Integrated Risk Information System (IRIS) scientific materials, including both qualitative and quantitative analyses and syntheses of human data and exposure information as identified in the contract performance work statement, Sections A(1 and 2); B(1,2,3,4 and 5); C (1); D and G (1 and 2).

#### II. BACKGROUND

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates quantitative and qualitative risk information on health effects that may result from exposure to environmental contaminants. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic non-cancer health effects, and oral slope factors and inhalation unit risks for carcinogenic effects. IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. By combining IRIS toxicity values with specific exposure information, government and other entities use IRIS to help characterize public health risks of chemical substances and thereby support risk management decisions designed to protect public health.

The IRIS Program is currently developing the 2014 IRIS agenda. The draft list of chemicals anticipated to appear on the agenda is provided in Appendix A. Assessments for some of these chemicals are in progress and others will be initiated in the coming fiscal years. In response to the evolving needs of EPA's Program Offices and Regions and IRIS Program resources, additional chemicals may be added to the agenda, and some chemicals may be dropped. Scheduling of chemical assessments will depend on a number of factors, including regulatory/ programmatic priorities, availability of staff and other resources, and potential public health impact of an assessment. Therefore, the IRIS Program will need to preserve flexibility in determining which assessments, whether the chemical is listed in Appendix A at this time or not, will require assistance during the period of performance of this Performance Work Statement (PWS).

#### III. SCOPE OF WORK: TASKS AND DELIVERABLES

#### Requirements Specific to this Work Assignment

Under this WA, an episode of work (aka "request") will be initiated by written Technical Direction (TD). Each request will clarify deadlines for delivering drafts and final work products. An initiating TD will identify the data and the specific Tasks (as outlined below) to be performed.

The Contractor shall prepare documents in the format specified in the current IRIS standard operating procedures and templates (to be provided by EPA). Recent examples of final and draft assessments for other chemicals may also serve as models. Documents shall be technically edited for format and grammar before being delivered to the EPA Work Assignment Manager (WAM).

The Contractor will be given an account in HERO (Health and Environmental Research Online), with access to scientific literature. Copyright law of the U.S. (Title 17 U.S. Code) governs the making of reproductions of copyrighted material. Section 107 of the copyright act instructs that, "the fair use of a copyrighted work for purposes such as ... research, is not an infringement of copyright." The Contractor is liable for any infringement of copyright. To set up the HERO account, the Contractor shall send an email to <a href="hero@epa.gov">hero@epa.gov</a> - and include the following information: Names, addresses, phone numbers, emails of all contractors needing HERO accounts, project name, start date and end date. The contractors will receive their HERO account information, with user documentation, within 3 business days.

HERO shall be used for performing literature searches. The literature search shall include, at a minimum, the following databases: PubMed, Web of Science, ToxNet; but may include others, as appropriate. The results from the literature search shall be submitted to HERO, as described in the user documentation. EPA will provide the PDFs through the HERO interface.

The Contractor shall use HERO (Health and Environmental Research Online) for reference citation and bibliographic generation, as described in the user documentation.

The Contactor will develop and maintain internal documentation and data pertaining to all assumptions, data sources, databases, procedures, statistical analyses, and computer programming code, scripts, and software instructions used to support and execute EPA's requirements and deliverables, in order that results can be replicated. The contactor will provide access to this internal documentation upon request by the EPA WAM or EPA Project Officer.

#### Task 1: Develop a Work Plan

The Contractor shall prepare a written work plan proposing a technical approach to the work assignment. The work plan shall outline how the work shall be performed and provide a list of deliverables and interim deliverables with the schedule for completion. In addition, the budget and staffing plan and a brief description of the qualifications of the key technical staff shall be included. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

Deliverable Schedule: Work plan due in accordance with the contract.

#### Task 2: Quality Assurance Project Plan (QAPP)

The contractor shall prepare a Quality Assurance Project Plan (QAPP), stating that the QAPP will be observed during the conduct of this work assignment.

The QAPP shall be submitted simultaneously with the work plan for approval. The contractor shall not perform any work under the other tasks of this Project until the contractor receives a signature page from EPA for the QAPP, showing approvals by the Work Assignment Manager, the contract Project Officer, and NCEA's QA official.

The Contractor shall provide EPA materials to the selected expert(s). This material will include a copy of the QAPP.

Deliverable Schedule: QAPP should be submitted no later than work plan.

#### Task 3. Kick-off Conference Call

Within 2 days after QAPP approval (or earlier if needed), the Contractor shall schedule a conference call with the WAM to discuss all tasks and to clarify any specific issues. The Contractor shall distribute meeting minutes of the topics discussed and any action items agreed to within 3 days after the conference call.

Deliverable Schedule: Conference call scheduled within 2 days after QAPP approval.

# Task 4: Manage, Identify and Recruit Expert Epidemiologists

The Contractor shall identify, recruit and manage expert epidemiologists ("experts") to develop sections of IRIS Toxicological Reviews and/or related materials. The Contractor shall be responsible for ensuring timely communication is passed between the EPA work assignment manager (WAM) and the experts so that technical clarification can be offered and interaction between EPA and the experts can occur as needed. The Contractor shall also ensure that the deliverables are provided to the EPA WAM in a timely manner.

EPA seeks to identify and recruit experts to develop several document sections/types for several different chemical assessments. These sections are discussed further in Task 5 within this WA, and they include:

- 1) Evaluation of exposure methods in epidemiological studies;
- 2) Study methods evaluations;
- 3) Evidence tables of specific health effects;
- 4) Graphical displays of evidence of specific health effects;
- 5) Other epidemiologic support (quantitative analysis, expert opinion, white papers, etc.).

EPA will provide guidance for the development of evidence tables and templates of the evidence and summary tables. The chemical assessments and related documents that will require assistance under this PWS will be clarified through technical direction.

The EPA assumes primary authorship in the writing process for all materials and contributing experts are listed in the final documents as appropriate. EPA will approve each of the experts performing work within two days of notification of a potential candidate.

#### **Subtasks**

# 1) Identify and Recruit Expert Epidemiologists

The Contractor shall identify and contact experts with a knowledge base that is aligned with the descriptions in each written TD. Each TD will specify the minimum/desired qualifications of the experts for that chemical assessment. The expertise needed will be specific to the broad field of epidemiology. Approximately 6-10 experts will be needed. Potential experts shall be asked to submit a bio-sketch to ensure they meet the minimum/desired qualifications, and EPA will notify the contractor of its concurrence with the selection.

# 2) Manage Expert Epidemiologists

The Contractor shall manage the recruited experts and ensure timely communication occurs between EPA and the experts. This shall involve setting up conference calls with the experts and EPA staff. In addition, the Contractor shall ensure that the written sections, comments and draft reviews are progressing on schedule and are delivered by the deadlines noted in this WA.

Deliverable Schedule: The schedule and specific expertise requested will be clarified within a TD.

# Task 5. Complete Subtasks as Directed by EPA

The specific subtasks under this PWS, identified in Task 4, are described below. Specific clarification will be provided by the EPA WAM through Technical Direction. Technical Direction will be submitted individually for each chemical assessment or project, and the subtasks to be completed will be project-specific (i.e., not all of the subtasks will be completed for each project). EPA estimates that up to 6 work products related to one or more of the 5 primary tasks described below will be required over the period of performance of this PWS.

For some tasks (in particular subtasks 2 and 3 below), the Contractor may be asked to provide their work product using a database format. The database, and any necessary training or guidance on how to populate the database, will be provided to the Contractor by EPA.

- 1) Evaluation of exposure methods in epidemiological studies. The Contractor shall provide and manage experts to provide guidance and clarification regarding interpretation of exposure measures in epidemiological studies. This will include conducting a review of the reliability and validity of methods used in selected primary source studies, focusing on issues of nondifferential and differential misclassification. A tabular or draft synthesis of conclusions regarding different types of exposure measurement methods may be requested.
- 2) <u>Study methods evaluation</u>. The Contractor shall provide and manage experts to abstract relevant details pertaining to methods and other details of individual studies to allow for evaluation consistent with the systematic review process. The purpose of this task is to evaluate studies with respect to potential methodological considerations that could affect the interpretation of or confidence in the results by applying a series of specific questions, and documenting study evaluation in tables.

Study methods evaluations should be independent of considerations regarding the direction or magnitude of study results. Study methods evaluations will be performed at an early stage of assessment development, i.e., after identifying the relevant sources of primary data but before developing evidence tables and characterizing hazard associated with chemical exposure. EPA will provide templates or database for the Contractor to use in abstracting study information. The specific details as to what should be abstracted will be determined through consultation with the EPA WAM.

- 3) Evidence tables. The Contractor shall provide and manage experts to prepare evidence tables that summarize results from epidemiologic studies, consistent with the draft *Handbook for IRIS Assessment Development* and *Elements of an Evidence Table* (Appendix B). The Contractor shall also conduct quality assurance (QA) checks of evidence tables developed by the experts and/or provided by EPA that shall include the following: comparison of table entries to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m³), confirming reported exposure ranges and effect measures, and inserting and verifying HERO links. The quality assurance checks should be performed by an expert that was not involved in the initial development of the table. EPA will provide the most current evidence table template or database for the Contractor to complete the task.
- 4) <u>Graphical displays</u>. The Contractor shall provide and manage experts to prepare graphical displays of results from epidemiologic studies. Approaches used for categorical exposure data (e.g., forest plots) and approaches used for quantitative data (e.g., representing magnitude of exposure or exposure contrast in relation to magnitude of effect) may be requested; the Contractor will provide expertise to develop or modify graphical displays ass needed. The Contractor shall also conduct quality assurance (QA) checks of the data used to generate graphical displays that shall include the following: comparison of data to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m³), and inserting and verifying HERO links. The quality assurance checks should be performed by an expert that was not involved in the initial development of the graphical display.
- 5) Other epidemiologic support. The Contractor shall provide and manage experts to address other issues that may arise within the context of the review of epidemiologic studies. These issues may pertain to ascertainment of specific outcomes in epidemiology studies, assessment of potential for confounding (e.g., through knowledge of co-exposures in specific workplaces or communities), and other questions regarding bias. This may also include quantitative modeling of epidemiologic data.

<u>Deliverable Schedule</u>: In general, work products shall be delivered in the following formats: tables for subtasks 2, and 3 and text for all remaining subtasks. The deliverable schedule will vary depending on the subtask(s) and chemical, and will depend on the amount and complexity of the information to be evaluated/summarized. The schedule will be clarified within a TD.

#### Task 6. Revision of Task 5 Deliverables

EPA will submit comments on the Task 5 deliverables. The Contractor shall provide and manage expert epidemiologic expertise to revise those deliverables based on EPA comments. The use of "redline" versions (track changes) of the document will be employed throughout the process. Tasks issued under this WA will be completed when all EPA comments have been considered and addressed, and may require multiple rounds of revision.

<u>Deliverable Schedule</u>: The deliverable schedule will vary depending on the subtask(s) and chemical. Unless otherwise specified in the TD, the Contractor will incorporate EPA comments within 7 days of receipt. The schedule will be clarified within the TD.

#### V. SCHEDULE OF DELIVERABLES

This schedule and the deliverables dates specified under each Task above may be further clarified using written Technical Direction.

Task	Schedule (*all days are elapsed calendar days unless otherwise stated)
1. Develop a Work Plan	In accordance with contract
2. Quality Assurance Project Plan	No later than Work Plan submission
3. Kick-off Conference Call	Scheduled within 2 days after QAPP approval
4. Manage, Identify and Recruit Expert Epidemiologists	To be clarified in written technical direction.
5. Complete Subtasks as Directed by EPA	To be clarified in written technical direction.
6. Revision of Task 5 Deliverables	To be clarified in written technical direction.

#### VI. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

#### VII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

# VIII. EPA CONTACTS

EPA Work Assignment Manager (WAM) Amanda S. Persad, PhD, DABT 919-541-9781 persad.amanda@epa.gov

Mailing Address: U.S. EPA, ORD/NCEA (Mail Drop B-243-01) RTP, NC 27711

Courier Deliveries: U.S.E.P.A. Office of Research and Development, National Center for Environmental Assessment MD B-243-01 4930 Page Road, Durham, NC 27703

EPA Alternate Work Assignment Manager (Alt-WAM) Audrey Galizia, PhD 732-906-6887 galizia.audrey@epa.gov

# Appendix A. Draft IRIS Agenda

Potential Chemicals List *To be updated as needed	CAS No.
acetaldehyde	75-07-0
acrylonitrile	107-13-1
ammonia	7664-41-7
arsenic, inorganic	7440-38-2
benzo(a)pyrene	50-32-8
n-butanol	71-36-3
tert-butanol	75-65-0
chlorobenzene	108-90-7
chromium VI	18540-29-9
1,4-dichlorobenzene (1,4-DCB)	106-46-7
diisopropyl ether (DIPE)	108-20-3
dinitrotoluene, technical grade	25321-14-6
ethylbenzene	100-41-4
ethyl tertiary butyl ether (ETBE)	637-92-3
ethylene oxide (inhalation, cancer)	75-21-8
formaldehyde	50-00-0
hexabromocyclododecane (HBCD)	3194-55-6, 25637-99-5
hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)	121-82-4
isopropanol	67-63-0
Libby amphibole asbestos	1332-21-4
manganese	7439-96-5
mercury, elemental	7439-97-6
methylmercury	22967-92-6
methyl tert-butyl ether (MTBE)	1634-04-4
naphthalene	91-20-3
perfluorooctanoic acid (PFOA)	335-67-1
perfluorooctanesulfonic acid (PFOS)	2795-39-3
phthalates	2175 57 5
butyl benzyl phthalate (BBP)	85-68-7
di-n-butyl phthalate (DBP)	84-74-2
diethyl phthalate (DEP)	84-66-2
di(2-ethylhexyl) phthalate (DEHP)	117-81-7
diisobutyl phthalate (DIBP)	84-69-5
diisododecyl phthalate (DIDP)	40989-56-8
diisononyl phthalate (DINP)	68515-48-0 and 28553-12-0
dipentyl phthalate (DPP)	131-18-0
polychlorinated biphenyls (PCBs) (noncancer)	various
polycyclic aromatic hydrocarbon (PAH) mixtures	various
tert-amyl methyl ether (TAME)	994-05-8
tert-amyl ethyl ether (TAEE)	919-94-8
trimethylbenzenes (1,2,3-,1,2,4-, and 1,3,5-isomers)	
uranium (natural)	7440-61-1
vanadium, elemental and compounds	various
vanadium pentoxide	1314-62-1
vanadiani pentonide	1317 02 1

# Appendix B. Elements of an Evidence Table (for IRIS Assessments)

Evidence tables are an integral part of IRIS assessments. The first iteration of evidence tables is presented in Stage 1 of the IRIS process (Draft Development) as part of the "Preliminary Package" of public materials. Further iterations or versions of evidence tables are included at later stages of the IRIS process, and may vary depending upon the chemical database and needs of the specific assessment. General elements common to all evidence tables are described below; other elements (including those pertaining to study quality evaluation) may be added to the evidence tables and will vary in content and format to allow for the compilation of the most suitable approach for the respective body of information. These specific elements will be determined by the assessment team with consideration from the scoping and problem formulation process and members from the appropriate workgroup.

#### I. General elements:

All evidence tables should include the following:

• **Author, year and location of study**: reported in as much detail as possible – country/region, state, city, specific factories, etc.

Hayes et al. (1979) (United States)

- **Study description:** Present study design type, sample size, description of study participants and controls or reference group
  - O Study design type: type of study with additional information as follows:
    - Cohort length of follow up, % lost to follow up
    - Case-control information on matching if performed
  - Sample size: the number of individuals or study units (e.g., couples, mother-child pairs) in various groups
     (may include: participation rate and data used in this derivation such as the number of participants recruited, number meeting selection criteria, number in final analysis/analyses, etc.)
  - Study population: This description should include:
    - Any relevant information on how the study population was selected (e.g., factory employment records), including any restrictions or inclusion/exclusions criteria (e.g., only workers with >1 year of job tenure)
    - Information on important demographic characteristics such as distribution of sex, age, and other
      outcome-specific factors (e.g., for pregnancy outcomes, may want to include parity; for lung cancer,
      may want to include smoking status)

Case-control study, 56 couples from assisted reproduction center, n=56 control couples (parents), mean age 39 years in both groups.

- Exposure assessment: Present how exposure was assessed (e.g., job exposure matrix, air sampling, etc). Also provide some measure of exposure levels (e.g., the mean and range of urinary concentrations of the chemical) for the study population, and/or for each group (e.g., the mean and range among the low and high exposed, or among cases and controls) if available.
- Outcome assessment: Present how was the outcome measured/evaluated (e.g., medical record, self-report, physician examination) and the degree that all cases were ascertained.
- Analysis: Present statistical methods (including any adjustment variables considered or used in the final analysis), and how results were evaluated. This should include details on how confounding was addressed as well as a description of how statistical significance/precision was evaluated (e.g., use of confidence intervals and/or significance tests).

Proportionate mortality (cancer) ratios, using the U.S. general population to generate expected mortality, adjusted for age, time period of death

• **Results:** Present overall or stratified results as available and appropriate, including any corresponding confidence intervals and/or p-values. If no quantitative results are available, a statement on the results as reported by the author will be provided, making clear that this is the authors' report and not EPA's judgment of results.

Authors note a marked increase in the prevalence of respiratory irritation among exposed workers.

# II. Other considerations for exhaustive):

generation of evidence tables (not

- **Table Format**: Modifications may be made to the table format depending on the specific database and needs of the assessment. For example, evidence tables may have 2 or 3 columns with the additional column designated for 'Exposure.'
- **Reporting information**: If information is not available, state that it is not reported (e.g. "Outcome: cardiovascular disease (ICD codes not reported)" or "Follow-up time not reported"]
- **Process/Interim Drafts**: It is suggested that the contractor provide an interim draft early in the development process (with about 5 study entries) for review by the epidemiology workgroup. This will allow for early feedback to the contractor prior to the completion of the evidence tables. Further feedback and discussion between the contractor and the epidemiology workgroup is expected throughout the development and evolution of the evidence tables.

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# PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-32

<u>TITLE</u>: Technical editing and augmenting evidence tables and exposure response arrays for Butyl Benzyl Phthalate (CASRN: 85-68-7)

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

1. Human Health Assessment Documents; E. Risk Assessment Support; F. Information Management

PERIOD OF PERFORMANCE: CO award to 10/31/14

#### I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of revisions to the draft IRIS Toxicological Review of Butyl Benzyl Phthalate (BBP). The overall objective of this WA is to obtain support from ICF in augmenting the evidence tables and technical editing the exposure response arrays for the IRIS Toxicological Review of Butyl Benzyl Phthalate (BBP). This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

# II. BACKGROUND

IRIS is an EPA data base containing Agency scientific positions on potential adverse human health effects that may result from chronic (or lifetime) exposure to chemicals in the environment. IRIS currently provides health effects information on over 500 chemical substances.

IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

EPA holds bimonthly public meetings to provide an opportunity for input and discussion on preliminary materials for IRIS chemicals prior to the development of the assessments. The objective of this public meeting is to obtain input from stakeholders and the public on the studies and data that may be used to characterize hazard and exposure-response relationships and to develop toxicity values. Specifically, EPA is seeking input on preliminary materials including draft literature searches and associated search strategies, evidence tables, and exposure-response arrays for chemicals prior to the development of the IRIS assessments.

The overall goal of the human health risk assessments is to provide scientifically-defensible reasoning for the choice of critical cancer and non-cancer effects due to chemical exposure, along with the literature and principal study(ies) that best represent and support that choice. The Work Assignment Manager (WAM) will provide technical direction as necessary.

### III. STATEMENT OF WORK

#### Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

# Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance Project Plans (QA/R-5)," http://www.epa.gov/quality/qs-docs/r5-final.pdf; and "A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information" and its Addendum, <a href="http://www.epa.gov/stpc/assess.htm">http://www.epa.gov/stpc/assess.htm</a>. The QAPP shall be submitted simultaneously with the Work Plan for approval.

Task 3: Updating and augmenting evidence tables and formating the exposure response arrays for Toxicological Review of Butyl Benzyl Phthalate (BBP). Update evidence tables with data from approximately 20 studies identified in recent literature search updates. Augment existing evidence tables with additional data provided during the QA of the evidence tables (spreadsheets with data to be provided by EPA). Technical editing of the exposure response arrays may include: standardizing symbols; verifying and restyling reference citations where required; cross-checking information in the exposure response arrays as well as correcting errors in grammar, spelling, and punctuation. Reformatting exposure response arrays to a style consistent with the current IRIS exposure response array format. Work in this task shall be performed according to EPA guidance related to the technical editing and preparation for publication of Toxicological Reviews, the draft Handbook for IRIS Assessment Development, and the current version of the evidence table template and exposure response template. The Handbook for Preparing EPA Documents shall be used as a primary reference to resolve issues involving usage and style. Specifically, this task includes:

- a. Update, augment, and edit evidence tables for format Add data from new studies (~20) and missing study data from excel spreadsheets into existing evidence tables. However, do not alter the sequence with which studies are presented in each table.
- b. Update, augment, and edit exposure response arrays for format –Add data from new studies identified in literature search updates and missing study data as well as correct exposure response array format and style to be consistent with the current IRIS exposure response array template. Technical editing of text in exposure response array. Ensure that data reported in the revised arrays

matches those provided in the original array format. However, do not alter the sequence with which studies are presented in each array.

- c. Summarize the mechanistic studies (~100) identified in the literature- Develop a table including information on the model system and specific assays used, route evaluated, general target tissues or systems studied, and endpoints reported. QA tables developed.
- d. HERO links Ensure that HERO links are functional in the revised work product. When necessary, add citations to the evidence tables using LitCiter. When using LitCiter, only use the HERO BBP library titled "BBP (Butyl benzyl phthalate) 2012".

# IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [\*.(d), \*.out, \*opt, \*.ssn]).

### V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	Per contact requirements •
Task 3. Update and augment evidence tables,	Approximately 4 weeks after EPA's submission of the
reformat exposure response arrays, develop	document to ICF
mechanistic tables	

Note: All days are calendar days.

# VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

# VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

## VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

# IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

# **Work Assignment Manager (WAM):**

Andrew K. Hotchkiss Telephone: 919-541-4164

Fax: 919-541-2985

e-mail: hotchkiss.andrew@epa.gov

Mailing Address: U.S. Environmental Protection Agency Mail code B-243-01 RTP, NC 27711

Overnight Delivery location: U.S. Environmental Protection Agency (B243-01) 4930 Page Road Durham, NC 27703

# Alternate Work Assignment Manager:

Teneille Walker

Telephone: 703-305-0563

Fax: 703-347-8689

e-mail: walker.teneille@epa.gov

Mailing Address: Two Potomac Yard (North Building) 2733 S. Crystal Drive Arlington, VA 22202

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# PERFORMANCE WORK STATEMENT CONTRACT EP-C-14-001 WA 0-33

TITLE: Science Technical Support for Analysis of Opportunities for Assessing and Addressing Cumulative Risks and Impacts by EPA Programs and Regional Offices

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD of PERFORMANCE: CO approval through October 31, 2014

#### I. PURPOSE

The purpose of this work assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Research (NCER) and the EPA Risk Assessment Forum (RAF) for developing technical and policy analyses and papers on cumulative risk and cumulative impacts.

#### II. BACKGROUND

Multiple aspects of the environment in which we live, learn, work, and play impact our health. Addressing multiple exposures to chemical and nonchemical stressors and cumulative risks and impacts in environmental decisions has long been a challenge for EPA and a concern of communities and environmental justice organizations. EPA's National Center for Environmental Research (NCER) is funding extramural research to develop methods and strategies for assessing the combined effects of chemical, physical and biological stressors while factoring in population vulnerabilities see http://www.epa.gov/ncer/cra/. EPA's RAF is currently developing Agency guidelines on cumulative risk assessment, building upon existing methods for chemical mixtures risk assessment routinely employed by EPA programs and regions. EPA's CRA Guidelines will advance the science further, introducing additional quantitative and qualitative analytical strategies for examining combinations of multiple chemical, physical and biological stressors and understanding how to factor in population vulnerabilities, including socio-economic stressors. NCER and RAF Cumulative Risk Technical Panel recently collaborated on a successful 1 ½ year CRA Webinar Series that focused on methods for assessing cumulative risk and decision frameworks. Although there is strong public interest for EPA to not only conduct cumulative risk assessments and use the results in decision making, institutional and policy barriers at EPA may prevent the full incorporation and use of cumulative assessment in environmental decision-making by EPA. Therefore, ORD/NCER and the RAF seek technical and analytical services to address technical and policy issues as follow-up to the CRA webinar series.

# III. STATEMENT OF WORK

# A. Objective: cumulative risk assessment (CRA) in statutory authority and implementation by EPA program offices and regional offices.

The purposes of this work assignment are to obtain services to support: 1) the development and preparation of manuscript(s) addressing how EPA program and regional offices use CRA, 2) a characterization of the decisions that are being informed by CRA, and 3) what interpretation of statutory authority is relied upon.

The work under this WA includes completion of the review of national statutory and regulatory requirements on cumulative risks/impacts assessment and the development of a manuscripts for these tasks to be submitted to a scientific journal. The contractor shall reference, apply and use data sources and analysis methodology prepared under WA-01 and 05 under EPA Contract EP-W-04-049.

# B. Specific Requirements

# Task 1: Analysis of Opportunities for addressing Cumulative Impacts in EPA Enabling Statutes The Contractor shall complete a review and synthesize all EPA enabling statutes as to the risk-based requirements for decision making and to what extent discretion is allowed to consider cumulative risks/impacts. Background documents include the Environmental Law Institute's publication "Opportunities for Advancing Environmental Justice: An Analysis of U.S. EPA Statutory Authorities" (see http://www.elistore.org/reports\_detail.asp?ID=41&topic=Environmental\_Justice) and CalEPA's CUMULATIVE IMPACTS: BUILDING A SCIENTIFIC FOUNDATION (see http://www.oehha.ca.gov/ej/cipa081910.html). The Contractor shall draft a report presenting the findings from the comprehensive review of the statutory authorities and revise the report based on EPA internal review comments.

The Contractor shall also develop manuscripts for publication on opportunities to address cumulative impacts under the Clean Water Act (CWA), Safe Drinking Water Act (SDWA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Previous analysis by the Contractor focused on the legal framework that courts use to evaluate EPA discretion to address cumulative risk. For this task, the Contract shall develop additional manuscripts describing how that framework might be applied under specific statutes. The manuscripts shall include summary tables of the statutory provisions. Contractor shall provide revisions based on journal peer review comments. Manuscript formatting shall include adjusting styles or references, section heading, tables and graphics as needed to conform to guidelines of appropriate scientific journals or EPA report styles. Final coordination of manuscript shall follow editorial requirements under Task 3.

Task 2: Analysis of Cumulative Risk Assessment use by EPA Program and Regional Offices
While there may be statutory authority for using cumulative risk assessment or analysis in decision
making, each EPA program and regional office may apply their own interpretation and develop policies
and guidance regarding cumulative risk to suite their specific needs. The Contractor will complete an

analysis of how cumulative risk assessment is currently used by EPA program and regional offices. The Contractor will draw upon information provided by EPA, a narrowly targeted literature review, as necessary, and interviews with approximately 20-30 EPA and independently identified EPA staff. The Contract shall conduct the analysis to answer the following questions:

- 1. What EPA programs use CRA, and for what precise programmatic purpose?
- 2. What decisions are being informed by CRA for the purposes identified in #1, above?
- 3. What statutory authority is associated with the use of CRA in #1, above, and are there interpretations of statutory authority or rules relied upon to permit the incorporation of CRA information into decision making?

The Contractor will provide an outline for EPA review and comment, a draft monograph for review, a final draft for review, and a final approved manuscript. Final coordination of manuscript shall follow editorial requirements under Task 3. The Contractor shall communicate regularly with EPA COR (and technical advisor/s) to ensure suitable detail, focus and rationales.

An illustrative process for discovery might proceed as follows: A listing of EPA programs using CRA are identified from the literature or through the COR. A preliminary hypothesis about how CRA is addressed in research Qs #1-3 is developed for each program. Program contacts are identified and initial email connection addressed to determine if they are the right person to interview, or to ID correct person. Interviews are conducted by phone asserting hypotheses to interviewees (assumed not to exceed 45 minutes in length). Corroboration with additional detail, or correction to hypothesis is gained from interviewee/s. It is appropriate to email the summary of the interview to the interviewee for their corroboration, but the interviewee's signed approval is not necessary. Calls may or may not be recorded, dependent on the contractor's need and at the option of the interviewee. Information on each interviewee should be appended to the report: Name, Office/Div./Branch, phone #, date of interview. In instances where conference calls are arranged with multiple participants, a list of all participants on the call should be included. A draft manuscript is sought for task #2 by July 7

#### Task 3: Scientific/Technical Editorial Services -

The Contractor, as directed by the WAM through written technical direction, shall develop technical manuscripts based on work conducted under Tasks 1 and 2. The contractor shall provide both science/technical editorial services for the final copy of manuscripts generated. The range of editorial services shall include a review of each paper for meaning, formatting, and assuring that papers meet publisher style requirements, spelling and grammar checks, researching references for accuracy, formatting bibliography, checking text for clarity, and formatting of graphics such as charts, symbols, and equations. The contractor shall discuss recommended edits for each paper with the authors, following a consultation with the WAM, and prior to incorporating edits.

After science/technical editing, the contractor shall send a copy of each paper and a summary report of all significant amendments in response to comments, or changes effected through the science/technical editing process or otherwise to the WAM. The WAM and other EPA staff identified by the WAM will review the final manuscripts over a 21 day period. At the end of the EPA review, the WAM will send the

manuscripts and any additional comments to the contractor. Upon receipt of the comments, the contractor shall consult with the authors on significant comments. The contractor shall edit the manuscripts according to the Technical WAM's comments.

The contractor shall finalize all manuscripts and submit camera ready copies of the manuscripts to the WAM in both pdf and MS word formats after incorporating the final comments from the WAM. The contractor shall also provide hard copies of each manuscript

# IV. SCHEDULE OF DELIVERABLES

- 1. The contractor shall send EPA all reports in accordance with the terms of the basic contract
- 2. The contractor shall provide a work plan within the schedule provided in the basic contract. If oral briefings are scheduled for EPA staff, the PO shall be notified in time to attend.
- 3. Outputs from data analysis and indicator preparation may include charts, graphics, MS Excel files and descriptive text.
- 4. Formatted manuscripts due one week after draft manuscripts provided to contractor.
- 5. Formatted EPA reports due two weeks after draft report provided to contractor
- 6. Revised manuscripts/reports due two weeks upon receipt of comments from WAM

#### VI. Other Requirements

Periodic meetings between the EPA and contractor work assignment managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WAM's discretion, these meetings may occur via teleconference or video conferences. The Contractor shall document these meetings and submit copies of this correspondence to the EPA WAM.

The EPA WAM may identify one or more EPA technical representatives for this work assignment. Interaction between the contractor and any EPA technical representative(s) designated by the PO is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. These interactions do not result in direction to the contractor.

All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

# VII. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

# VIII. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

#### IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

#### X. Work Assignment Manager (WAM)

Lawrence Martin
Science Coordinator
Risk Assessment Forum
U.S. EPA Office of Science Advisor
1200 Pennsylvania Avenue, N.W. (8105-R)
Washington, DC 20460
voice - 202.564.6497

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## PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-34

# **TITLE: Technical Editing Support of Risk Assessment Forum Documents**

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD OF PERFORMANCE: CO award to 10/31/14

#### A. BACKGROUND

Federal regulatory agencies often rely on risk assessments as a primary component in their decision-making process. To ensure that assessments are conducted in a consistent and transparent manner the Environmental Protection Agency develops guidelines, guidance documents and "white papers" to provide a framework for analyzing data. EPA's Risk Assessment Forum (RAF) is charged with coordinating the development of Agency-wide guidelines and guidance documents that provide that framework. The principal audience for these products are EPA risk assessors and risk managers; however, these documents also provide clarity and transparency to the stakeholders and other interested parties, and are often cited by other regulatory entities.

#### **B. PURPOSE**

As noted above, guidelines and related products are among the most important products generated by EPA. The intent of these products is to inform risk assessors how to acquire data and apply it to risk assessments; and to promote consistency in Agency risk assessments and inform stakeholders and other interested parties of EPA risk assessment policies and practices. As such, these documents need to be written in a clear and concise manner.

Technical editing follows the development of the content to improve the clarity of the message. The purpose of this work assignment is to edit and ensure consistency throughout the document in content and voice, avoid redundancy, and above all, ensure that the information is clearly and accurately presented. Depending upon the intended audience it is important that the document communicate at the appropriate level of sophistication. For the most part the document needs to primarily inform risk assessors of the Agency's methods and policies when performing assessments for the Agency but also communicate to other stakeholders.

This work assignment will serve as a generic task with the intention that it will cover technical editing of several documents for which technical direction will be issued for each product. The technical direction accompanying each document will contain instructions specific to the product.

#### C. KNOWLEDGE AND SKILLS REQUIRED

Although much of the content has been provided, it is essential that the contractor possess demonstrated experience in the production of quality EPA guidelines with an appropriate level of expertise in exposure science, human health and ecological risk assessment methods, to adequately critique and edit RAF documents for clarity and consistency, as well as providing grammatical editing. The level of expertise for each task will be commensurate with the technical direction.

#### D. TASKS

#### **Task 1: Establish Communication**

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the COR, workgroup members, and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks for the work assignment. Similarly, the Contractor shall initiate communication with the COR within three days of the issuance of a technical direction. The contractor shall initiate additional communication with the COR should developments arise that will affect the conduct or schedule of the assignment.

# Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in the technical direction under this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance Project Plans (QA/R-5)," http://www.epa.gov/quality/qs-docs/r5-final.pdf; and "A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information" and its Addendum, http://www.epa.gov/stpc/assess.htm. The QAPP shall be submitted simultaneously with the Work Plan for approval.

For the purposes of preparing the work plan/cost estimate, the contractor should assume performing editing on three (3) documents. The first document is a draft document of about 325 pages in total that will require significant review and editing (document, references and technical direction attached), a second document of about 70 pages requiring a review and search for formating, style and typographical errors, and possibly a third document of about 100 pages requiring a similar level of review.

#### Task 3. Technical Editing

The Contractor shall review and edit the document addressing grammatical, syntax, and spelling errors that may exist in the document with specific attention to the items listed in the technical direction. The technical direction may also include associated activities such as tabulating reviewers' comments on draft documents. The Contractor shall maintain ongoing communication with the COR to ensure quality and timely completion of the project.

#### Task 4. Delivery of the Final Product

The Contractor may deliver electronic versions (MS Word 2007) of the edited document to the COR, alternate COR, and others designated in the technical direction including both clean and marked drafts: the latter shall be a revised document presented as a "track changes.

#### E. SCHEDULE AND DELIVERABLES

Product	<b>Due Date</b>
Task 1. Initial Conference Call	3 days after award
Task 2. Staffing Plan, and QAPP	Per contact requirements

Task 3. Shall review and edit the document addressing grammatical, syntax, and	As specified in the technical
spelling errors that may exist in the document with specific attention to the items	direction.
listed in the technical direction laid out in the attachment.	
Task 4. Shall deliver an electronic version (MS Word 2013) of the draft document	As specified in the technical
to the COR, alternate COR, and others designated in the technical direction	direction.
including each in both clean and marked-up drafts: the latter shall be a revised	
document presented as a "track changes unless otherwise specified in the technical	
direction.	

#### F. Acceptance Criteria

Final products shall be produced by the Contractor upon the EPA WA COR's approval through written technical direction. The Contractor shall provide all materials written as part of these tasks to the EPA WA COR, as per work assignment, in electronic format. Electronic versions shall be in MS Word 2013, Powerpoint 2013 and Excel 2013 computer format as specified in the technical direction.

#### G. MANAGEMENT CONTROLS:

Periodic meetings between the EPA and contractor work assignment managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WA COR's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA WA COR.

The EPA WA COR may identify one or more EPA technical representatives for this work assignment. Interaction between the contractor and any EPA technical representative(s) designated by the EPA WA COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. The interaction will be technical communication vice technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO COR and the EPA WA COR or alternate EPA WA COR are the only representatives of the CO authorized to provide technical direction.

Per the technical direction clause, the CO and PO will be provided with copies of all technical direction.

#### H. CONFIDENTIALITY

Some of the information to be edited under this task may be internal information that is not ready for public distribution. The Contractor shall not discuss the contents of the document with anyone not specified as a participant in the document review process or its preparation.

#### VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

#### NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities

#### (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO , WAM or CO

#### **SPECIAL CONDITIONS AND ASSUMPTIONS**

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

#### **EPA CONTACT INFORMATION**

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

#### **Work Assignment Manager (WAM):**

Michael W. Broder Office of Science Advisor U.S. EPA (8105-R) Office of the Science Advisor 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460 Telephone: (202) 564-3393

Fax: (202) 564-2070

#### **Alternate Work Assignment COR:**

Lawrence Martin
Office of the Science Advisor
U.S. EPA (8105-R)
1200 Pennsylvania Ave., NW
Washington, DC, 20460
Telephone (202) 564-6497

Fax: (202) 564-2070

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# PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-35

TITLE: Workshop to Discuss Policy-Relevant Science to Inform EPA's Integrated Plan for the Review of the PM NAAQS

Principal Section & Paragraph of SOW: A. Assessment Issues and Documents

PERIOD OF PERFORMANCE: CO Approval – October 31, 2014

Note: This WA contains a description of work that is expected to take place in Option Period 1 as a follow-on WA. For purposes of the WP/Cost Proposal, the contractor shall only price work expected to take place in the current period of the contract, as evidenced in the deliverable table below.

#### I. PURPOSE

The purpose of this work assignment is to provide administrative and logistical support for a 3-day workshop, planned for February 10-12, 2015, to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA). This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

#### II. BACKGROUND

Sections 108 and 109 of the Clean Air Act require periodic review and, if appropriate, revisions of the national ambient air quality standards (NAAQS) and the air quality criteria on which they are based. EPA will initiate a review of the primary and secondary NAAQS for the effects of particulate matter (PM) in the summer of 2014. As part of this review, EPA will first develop a draft integrated plan that will outline the schedule, process, and key policy-relevant issues that will generally be used to frame the science assessment, risk/exposure assessment, and policy assessment documents. These documents will provide the foundation to inform Agency decision-makers throughout the review of the NAAQS for PM.

To facilitate the development of this draft integrated plan, EPA plans to hold a workshop on or around February 10-12, 2015 to receive input from internal and external PM experts. Workshop participants shall be asked to discuss current and emerging science that may inform the key policy-relevant issues. The workshop discussions will be considered as the Agency develops the draft integrated plan to incorporate the most current, policy relevant science into the NAAQS technical support documents briefly described above.

#### III. STATEMENT OF WORK

#### A. Objective

The overall objective of this work assignment (WA) is to provide administrative and logistical support for the workshop described above. The workshop will be 3 days in length. The goal of the workshop is to ensure that this review focuses on the key policy-relevant issues and considers the most meaningful new science to inform our understanding of these issues. As stated above, speakers/panelists will present a variety of perspectives and facilitate an open dialogue on policy-relevant issues with discussions focused on health effects associated with PM exposure. The workshop discussions will provide important input as EPA considers the appropriate design

and scope of the major elements of the PM review that will inform the Agency's policy assessment under the NAAQS process: as integrated plan highlighting the key policy-relevant issues; an integrated science assessment; and a risk and/or exposure assessment. Each session panel shall consist of several experts (EPA or non-EPA) from a range of disciplines including epidemiology, toxicology, clinical sciences, dosimetry, exposure assessment, and atmospheric chemistry, with additional expertise on welfare effects, specifically visibility. The workshop shall have an expected attendance of approximately 250 participants, both in-person and through a webinar, including non-EPA experts, and shall be held at the U.S. EPA RTP campus. Conference rooms have been reserved on the US EPA campus in RTP for February 10-12, 2015. If an alternative date becomes necessary and needs to be rescheduled, EPA will submit to the contractor recommended alternative date (s) for the workshop. Administrative and logistical support shall consist of the following tasks:

# B. Specific Requirements (Tasks)

- 1. A kick-off meeting shall be held (in person and/or by phone) between the Contractor and Contracting Officer Representative (COR) to clarify or address questions. The contractor shall maintain communication with the EPA COR through weekly phone calls or email updates.
- 2. The contractor shall develop a candidate list of non-federal experts with broad based knowledge and expertise in the areas that inform health effects of PM, including atmospheric chemistry, exposure assessment, epidemiology, toxicology, clinical sciences, and dosimetry; and welfare effects, including expertise on visibility and climate effects; along with expertise in risk/exposure assessment with the goal of recruiting approximately 20 of these experts to participate in the workshop. All experts should have an understanding of or experience with the NAAQS process. Potential invitees shall be asked to submit a bio-sketch to WA-COR for assessing their qualifications and to ensure they are sufficiently qualified in the proposed area of expertise (evidenced by education, experience, publications, etc.).
- 3. Once experts have been approved, the contractor shall formally invite each to the meeting.

# V. SCHEDULE OF DELIVERABLES

<u>Deliverables</u>	<b>Due Dates</b>
1. Initial contact (listed above) shall be performed	Within 3 days of award
2.List of candidates submitted to COR for approval	August 1, 2014
3. Invite experts for workshop participation	<u>September 30, 2014</u>
4. Establish website for online registration	September 30, 2014

# VI. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or COR.

# VII. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA COR at the initiation of the work assignment, and shall provide a weekly update to the COR by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on dates to be determined.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

# VIII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Contracting Officer Representative (COR)
Jen Richmond-Bryant, PhD
919-541-4518
richmond-bryant.jennifer@epa.gov

Alternate COR
Steve Dutton, PhD
919-541-5035
dutton.steven@epa.gov

#### Attachment 1

# Elements of a Quality Assurance Project Plan (QAPP) for Secondary Data and Analyses

#### 1. Title and Approval Page

Include signatures lines for the contractor, his/her quality system personnel, the NCEA project officer, and his/her quality assurance coordinator.

#### 2. Quality System Components

Describe the contractor's current organizational quality assurance program, including but not limited to:

- a. Who has responsibility for the quality control of projects?
- b. Where is this person in the organizational hierarchy?
- c. What quality control and assurance procedures are planned or in place for projects like the proposed, and are these procedures documented?
- d. How does the person responsible for quality assess and document the quality control exercised in projects and implement any necessary corrective actions, including those that require approval from the project's client?

#### 3. Project Definition and Background

This information may be found in the Statement of work or narrative for the contract.

#### 4. Data Quality Objectives (DQOs)

Include an explanation of data use and acceptance criteria (precision, accuracy, representativeness, completeness, and compatibility). Some of DQOs may be specified in the Statement of Work or narrative for the project.

#### 5. Project Organization and Responsibilities of the Researcher/Analyst

Briefly describe how the project will be executed and who has responsibility for the various tasks. List licenses, certifications, and accreditations that are applicable to this project. Document how any items and services procured under this project will be determined to be of good quality and applicable to the needs of this project.

#### 6. Project Description, Documentation, and Reporting

## **6.1 Description of Project Areas and Relative Quality Control Processes, including but not limited to** (*Note: Do not leave any of the items below bland; specify any item that does not pertain to this project*):

- a. Data analysis, including a rationale for the type and number of data runs; include software used and data analysis techniques employed;
- b. Compliance with any data input characteristics required by the project;
- c. Verification of the source and quality of the original data, including the quality control procedures used in the collection of the original data;
- d. Data characteristics and parameters such as: criteria for data acceptance or rejection and any modifications made to the original data necessitated by the present project;
- e. Input/output of data, data format conventions, data conversion issues, and data maintenance and archiving procedures; and
- f. Constraints placed on the data.

#### General Considerations and QA Requirements for the following issues:

- a. Source(s) of the existing (secondary) data/information and rationale for selecting the source(s); Sample selection, collection and preparation (describe the planning process for data gathering operations and how the organization ensures that data or information collected for a project are of sufficient quality to satisfy the needs of the project);
  - b. Non-quality constraints on the existing (secondary) data/information (e.g., legal, programmatic, CBI) that affect its use in the project;
  - c. How the data/information will be used in the project, e.g., augment or replace existing data/information, verify or validate existing data/information;
  - d. Procedures for determining the quality of the existing (secondary) data/information, i.e., how and to what degree will the accuracy, precision, representativeness, completeness, and comparability of the data/information be determined for the purposes of the project; what are the limitations or uncertainties associated with the data/information;
  - e. Reduction/validation procedures, including calculations and equations, for the existing (secondary) data/information that are specific to the project; (for secondary data gathered from publication, see the accompanying "Quality Assurance Instructions for Researchers Citing Secondary Information"); and
- f. Plans for review of the project during operation (oversight).

  (discuss how the contractor will test for quality problems with this project. Who is normally responsible for this process of testing? Who changes the methods within the project if change is indicated by these tests?).

#### **Quality Assurance Instructions for Researchers Citing Secondary Information**

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452, 2/22/02, underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its criteria and assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases and models. The set of processes that follows serves as a guide to evaluate the strength of secondary information gathered from these primary sources.

To begin, researchers must list the sources for the references they use. The source list will include but not be limited to the names of any commercially available or local databases of literature that the researcher searches by computer or by hand along with the search terms, search strategies, and time periods used in these searches. The list also will include any print sources such as books or journal articles which provided references from their respective bibliographies and databases or models of observational information related to the physical environment, effects on the ecosystem, or effects linked to human health.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate these studies. Key studies are those most crucial or pivotal to answer the research questions posed in the project. Though the key study may show only negative results or may even be all that is

currently available on the research topic, it is crucial, nonetheless, to any discussion of the topic. (In the case of databases or models or observational information, either may constitute a key study.) Sometimes, the key study is not recognizable until all of the information is gathered and sifted through. Key studies should exhibit at least most of the general attributes defined below, which bear comparison to the OMB guidelines to federal agencies mentioned above.

## 7. Reconciliation with Data Quality Objectives

Describe how issues which come up during the project and require adjustment to the DQOs will be resolved.

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## PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-36

TITLE: Technical Support for PARMS Science Team

Specify Section & Paragraph SOW: D - Analysis, Document and Issue Paper Preparation

PERIOD of PERFORMANCE: CO approval through 10/31/2014.

#### I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (EPA) Policy Analysis and Regulatory Management Staff (PARMS) Science Team, within the Office of Solid Waste and Emergency Response (OSWER). The specific purpose is to support the PARMS Science Team activities and efforts related to risk assessment and toxicology.

#### II. BACKGROUND

The PARMS Science Team provides technical support to various OSWER program offices. This support includes evaluation of toxicological and risk assessments information related to contaminated lands, and the beneficial reuse of waste materials. The PARMS Science Team works with a number of cross-Agency groups including the Risk Assessment Forum (RAF), Science and Technology Policy Council (STPC), and the Scientific Integrity Committee. It also works with a number of OSWER-led groups including the Technical Review Workgroups for asbestos, bioavailability, and lead, and the OSWER Human Health Regional Risk Assessors Forum (OHHRRAF). The PARMS Science Team support for these various groups includes the analysis of scientific information, and the development of issue papers, and other technical documents. Contract support for these activities will be provided through this WA.

#### III. SCOPE OF WORK: TASKS AND DELIVERABLES

#### Task 1: Work Plan Development

The Contractor shall prepare a written work plan describing how the tasks in this Performance Work Statement (PWS) will be performed, including a schedule, budget, level of effort, and qualifications of personnel. To facilitate timely preparation of the work plan, a kick-off meeting shall be held (in person and/or by phone) between the Contractor and the EPA WA Manager (WAM) to clarify or address questions. The Contractor shall maintain communication with the WAM through weekly phone calls or email updates.

**Deliverable 1:** In accordance with the contract.

#### Task 2: RAF-Related Support

Under this task, the confractor will work with the PARMS Science Team to develop technical materials related to two topics being addressed by RAF technical panels: cumulative risk assessment, and characterizing uncertainty and variability. For both efforts the Contractor will work with the PARMS Science Team to identify current practices in other parts of EPA, and outside organizations, and develop position papers on how

OSWER could expand its own efforts in the areas of cumulative risk and characterization of uncertainty and variability.

**Deliverable 2a:** The Contractor shall develop an issue paper on potential applications of cumulative risk assessment methodologies in OSWER.

**Deliverable 2b:** The Contractor shall develop an issue paper on potential applications of methodologies for characterizing uncertainty and variability.

## Task 3: Scientific Integrity Support

Under this task, the contractor will work with the PARMS Science Team to prepare technical materials related OSWER's implementation of the Scientific Integrity Policy, including the development of materials for a clearance procedure for scientific and technical work products.

**Deliverable 3:** The Contractor shall develop a clearance procedure for scientific and technical work products.

## Task 4: STPC-Related Support

Under this task, the contractor will work with the PARMS Science Team to prepare technical materials for the quarterly meetings of the STPC, and the STPC Steering Committee.

**Deliverable 4:** The Contractor shall provide technical materials for the quarterly STPC pre-briefings, and support the PARMS Science Team in addressing action items.

## Task 5: TRW-Related Support

Under this task, the contractor will work with the PARMS Science Team to prepare technical materials related to the TRW committees for asbestos, bioavailability, and lead. These technical committee have contract support to run their meetings, and prepare notes, and this task will provide additional support as directed by the WAM.

**Deliverable 5:** The Contractor shall develop technical materials related to asbestos, bioavailability and lead.

## Task 6: OHHRRAF-Related Support

Under this task, the contractor will work with the PARMS Science Team provide technical to support the OHHRRAF in a range of risk assessment related topics, including exposure and toxicology. The OHHRRAF meets by teleconference approximately bi-monthly. Technical support will include meeting support, including meeting summaries, and development of technical materials to address action items such as position papers.

**Deliverable 6:** The Contractor shall provide technical support to the OHHRRAF

#### IV. SCHEDULE OF DELIVERABLES

Deliverable	Schedule (*all days are elapsed calendar days unless otherwise stated)
1. Work Plan	15 days* after receipt of this WA
2a. Uncertainty and variability position paper	45 days after approval of Work Plan
2b. Cumulative Risk Assessment position paper	October 31, 2014
3. Scientific Integrity Support	60 days after approval of Work Plan
4. STPC-Related Support	To be specified in written technical direction
5. TRW-Related Support	To be specified in written technical direction
6. OHHRRAF meeting Support	To be specified in written technical direction

#### V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA. The Contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.

#### VI. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

#### VII. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in the contract.

#### VIII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The Contractor shall not engage in activities of an inherent governmental nature such as the following:

- 1. Formulation of Agency policy
- 2. Selection of Agency priorities
- 3. Development of Agency regulations

Should the Contractor receive any instruction from an EPA staff person that the Contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the Contractor shall immediately contact the PO or WAM.

#### IX. EPA CONTACTS

## EPA Work Assignment Manager (WAM)

Nicholas Hilosky

Telephone: (202) 566-1942

Fax: (202) 566-1934

E-mail: hilosky.nick@epa.gov

#### Mailing Address:

U.S. Environmental Protection Agency
Office of Solid Waste and Emergency Response

Mail Code: 5103T

1200 Pennsylvania Ave NW Washington,

DC 20460

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## PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-36 Amend 1

TITLE: Technical Support for PARMS Science Team

Specify Section & Paragraph SOW: D - Analysis, Document and Issue Paper Preparation

PERIOD of PERFORMANCE: CO approval through 10/31/2014.

#### I. PURPOSE

The purpose of this amendment to reduce the level of Contractor support on Task 6 by eliminating the meeting support. We would like them to retain the support on the technical documents.

## Task 6: OHHRRAF-Related Support

Under this task, the contractor will work with the PARMS Science Team provide technical to support the OHHRRAF in a range of risk assessment related topics, including exposure and toxicology. The OHHRRAF meets by teleconference approximately bi-monthly. Technical support will include meeting support, including meeting summaries, and development of technical materials to address action items such as position papers.

**Deliverable 6:** The Contractor shall provide technical support to the OHHRRAF

#### EPA Work Assignment Manager (WAM)

Nicholas Hilosky

Telephone: (202) 566-1942

Fax: (202) 566-1934

E-mail: hilosky.nick@epa.gov

Mailing Address:

U.S. Environmental Protection Agency

Office of Solid Waste and Emergency Response

Mail Code: 5103T

1200 Pennsylvania Ave NW Washington,

DC 20460

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## PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-37

TITLE: Collection, Evaluation, and Archival of Exposure-Related Information for Consumer Products

Specify Section & Paragraph SOW: D - Analysis, Document and Issue Paper Preparation

PERIOD of PERFORMANCE: CO approval through 10/31/2014.

Note: Most of the work outlined in this PWS will take place in the next option period, assuming it is exercised and follow-on issued. However, in order to give context to and properly scope the entire project, work is included in this PWS that is expected to take place in both period. It is expected that only Task 1 (Work Plan Preparation) and Task 2 will take place during this initial base year, with all other work being completed in a follow-on work assignment issued during Option Period 1.

That being the case, EPA would request that ICF prepare a technical work plan that addresses all work described herein (including that taking place in follow-on period); however, PEA also asks that ICF submit two separate cost estimates, one for this base period effort, and one for remaining effort using tentative deliverable dates contained herein.

#### Background

EPA has been developing novel approaches and tools for evaluating, screening and classifying chemicals for the Chemical Safety for Sustainability (CSS) Program based on the potential for biologically-relevant human exposures, for the purpose of informing toxicity testing and prioritization for risk assessment. Program Offices and other Stakeholders need the ability to readily use a flexible and integrated source to-dose-to-effects model with more realistic exposure modules for evaluating, screening and ranking risks from chemical exposures of different population and age groups.

NERL has developed an efficient and more generalizable high-throughput version of the Stochastic Exposure and Dose Simulations (SHEDS) modeling tool ("SHEDS-HT"). SHEDS-HT is being designed to fill critical gaps in data and numerical algorithms in order to comprehensively characterize key human exposure pathways within a multi-tier and efficient modeling framework. As part of a collaboration with NCCT's ExpoCast project, SHEDS results will be evaluated and incorporated into calibrated consensus exposure predictions within the Systematic Empirical Evaluation of Models (SEEM) framework.

The SHEDS-HT model is being parameterized for a large number of commercial chemicals present in consumer products, articles, foods, and drinking water. However, this parameterization effort requires the identification, collation, and documentation of many disparate sources of data related to consumer product use, composition, and purchasing.

EPA has also recently developed repository information related to chemical use, the Chemical and Product Categories (CPCat) Database, contained within NCCT's Aggregated Computational Toxicology Resource (ACToR). This database - which contains a variety of information related to the categorization of chemicals by functional, industrial, or other uses – is a high-value resource for developing and refining high-throughput exposure tools.

The focus of this project will be to collate and archive relevant exposure-related consumer product information from a variety of sources (in a documented, structured form) to support the development and expansion of SHEDS-HT, ExpoCast, and CPCat.

The WACOR is authorized to provide technical direction in accordance with the contract. This PWS instructs the Contractor to perform the tasks are described below.

## I. Description of Tasks

## Task 1. Develop Work Plans

The Contractor shall submit a work plan outlining the entire technical approach (all tasks) and base period cost estimate addressing Task 2 of this PWS, quality assurance procedures to be conducted, the schedule for the WA completion. Following review by the WACOR, should any changes be required, a final revised work plan shall be submitted by the Contractor within 7 days of receipt of WACOR comments and recommendations. The contractor shall also develop a second cost estimate which will address all remaining work to be completed in subsequent option period assuming it is exercised. This will be so the EPA can properly scope the entire project within its projected budget.

# Task 2. Collect, Document, and Archive Quantitative Exposure-Related Data from Danish Consumer Product Surveys

The Danish Environmental Protection Agency has conducted a large number of surveys of chemicals found in consumer products, incorporating information from manufacturer reporting, targeted manufacturer surveys, and laboratory assessments. Detailed reports are available for over 100 such surveys at <a href="http://eng.mst.dk/topics/chemicals/consumers-consumer-products/danish-surveys-on-consumer-products/">http://eng.mst.dk/topics/chemicals/consumers-consumer-products/danish-surveys-on-consumer-products/</a>. These reports contain potentially useful quantitative information related to product compositions (e.g. mass percent of chemical in products) or default/measured exposure factors (e.g. transfer of chemical to skin). The Contractor will collect from these reports such composition and exposure factor data and store it in a structured form provided by the WACOR. Other non-quantitative chemical use information (e.g. functional use of chemicals within products, simple presence/absence of chemical within product categories) should also be documented in a format consistent with CPCat.

The WACOR will provide guidelines for data or database formats (e.g. MySQL), for compatibility with EPA's ACTOR and/or CPCat databases, within 2 weeks of EPA issuing the WA to the contractor. The Contractor will deliver to the WACOR all numerical data, chemical categorizations, and appropriate metadata (original source location, etc.) extracted from the Danish reports in the designated database format. The Contractor will also prepare a brief technical memo describing the data collection, QA procedures, and any assumptions made. The Contractor will deliver the database and technical memo to the WACOR on or before October 31, 2014.

Task 3. Collect, Document, and Archive Consumer Product Ingredients from MSDS Sources EPA has previously collected consumer product ingredient information from a retailer-provided Material Safety Data Sheet (MSDS) repository (Goldsmith et al., *Food and Chemical Toxicology* 65:269-279, 2014). Methods were developed for 1) programmatically extracting the chemical ingredients, CAS numbers, and product names from MSDS sheets in to a MySQL database using custom scripts and 2) manually curating composition information for each product ingredient using a web-enabled interface.

The WACOR will provide a list of additional existing manufacturer, retailer, or industry group MSDS data sources to the Contractor. It is anticipated that these sources will comprise on the order of 1000-5000 MSDSs (products). The Contractor will use the methods of Goldsmith et al. (or similar methods) to extract product composition information from the MSDS sheets. The contractor will also assign to each identified product one or more consumer product categories consistent with CPCat or SHEDS-HT. In addition, data sources for information on chemical use (functional or otherwise) may be identified as well for automated data extraction. The WACOR will provide scripting tools, curation interface, and/or database format guidelines within 2 weeks of EPA issuing the WA to the contractor.

The Contractor will deliver to the WACOR all CASRNs, numerical composition data, chemical categorizations, chemical uses and/or appropriate metadata (original source location, etc.) extracted from the MSDSs or other sources in the designated database format. The Contractor will also prepare a brief technical memo describing the data collection, QA procedures, and any assumptions made. The Contractor will deliver the database and technical memo to the WACOR on or before December 31, 2014.

#### Task 4. Locate UPC Information for Consumer Products

EPA has recently obtained a proprietary database of consumer product purchases made within the U.S. This database contains product-level information, indexed by UPC code. To facilitate the merging of this database with consumer product chemical ingredients, the Contractor will obtain UPC codes (when available) for the approximately ~9000 consumer products contained in the EPA's Consumer Product Chemical Profile Database (CPCPdb). The UPC codes will be obtained via searches of publically available UPC databases or from retailer sites (via Google searches of product names).

The list of consumer products contained in the CPCPdb will be provided to the Contractor by the WACOR within 2 weeks of EPA issuing the WA to the contractor.

The Contractor will deliver to the WACOR a matched list of consumer products and UPC codes in Excel spreadsheet form on or before January 31, 2015.

## Task 5. Identify and/or Evaluate Additional Data Sources for Quantitative Exposure-Related Information

In addition to the Danish EPA and MSDS data sources described above, the Contractor will locate, evaluate, and document additional web-based public databases for high-value quantitative consumer product data. The WACOR will provide an initial list of data sources for evaluation; the Contractor will then search for additional publically available resources. The contractor will evaluate and document each data source with respect to: 1) quantity and quality of information describing chemical composition of products 2) types of products represented (e.g. consumer products, clothing, articles), 3) quantity and quality of information describing chemical use within products, 4) ease of data extraction (e.g. potential for scripting approaches versus manual curation), and 5) any other criteria communicated to the Contractor by the WACOR.

An initial list of candidate web-based resources will be provided to the Contractor by the WACOR within 2 weeks of EPA issuing the WA to the contractor. The Contractor will prepare a technical memo evaluating all identified data sources. The Contractor will deliver the technical memo to the WACOR on or before January 31, 2015.

## QA/QC Requirements for WA:

The WA-COR will develop an approved quality assurance project plan (QAPP) that will be provided to the Contractor prior to the Contractor beginning Task 2. The QAPP will be developed based on Chapter 3 for

projects using existing data within the EPA Guidance for QAPPs (EPA QA/G-5) that can be found here, <a href="http://www.epa.gov/quality/qs-docs/g5-final.pdf">http://www.epa.gov/quality/qs-docs/g5-final.pdf</a>. The QAPP will identify responsibilities of both EPA and the Contractor, and lay out quality objectives and criteria. Note that the Contractor may begin work on Task 1 (Work Plan development) prior to delivery of the QAPP. The Contractor will adhere to the QAPP when completing Tasks 2-5.

#### **Deliverables:**

A meeting shall be arranged and conducted by the Contractor to discuss the initiation of the tasks with the WACOR. Subsequently, phone conferences or meetings shall be conducted by the Contractor on a bi-weekly basis to discuss with the WACOR the progress and any issues associated with the tasks. The Contractor shall adhere to the following schedule:

Task	Deliverable	Delivery Schedule
1	Base Contract Period Work Plan and cost estimate	20 days after receipt of WA
2	Database of information from Danish consumer product reports and accompanying Technical Memo	October 31, 2014
3	Database of information from MSDS data sources and accompanying Technical Memo	December 31, 2014
4	Matched list of CPCPdb consumer products and UPC codes	January 31, 2015
5	Technical Memo describing evaluation/identification of additional consumer product data sources	January 31, 2015

## **Reporting Requirements:**

The Contractor shall provide monthly progress reports in accordance with the terms of the contract. In addition, the Contractor shall deliver to the WACOR any draft and final reports in electronic format that is readable by windows-based word-processing (Microsoft Word 2003), graphics (Microsoft PowerPoint 2003), spreadsheet (Excel 2003), and database (MySQL) programs.

Work Assignment Contracting Officer's Representative (WACOR):

WACOR: Kristin Isaacs Phone: (919) 541-2785

Alternate WACOR Name: Peter Egeghy

Phone: (919) 541-4103

U.S. Environmental Protection Agency

Office: ORS/NERL

Division (Mail Code): HEASD (E205-02)

109 TW Alexander Drive

Research Triangle Park, NC 27711

Phone: (919) 541-2785

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Other Age	ncy Offici	ial Name Ada	am Meier				Bra	nch/Mail C	ode:				
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